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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,987	11/03/2003	Wing-Kee Philip Cho	025444.1059-US02	5359

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,987	CHO, WING-KEE PHILIP	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73,75,80,81,90,93-96,99,101,105-109 and 117-121* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *93-96,106-109,119 and 120* is/are allowed.

6)☒ Claim(s) *73,75,80,81,90,99,101,105,117,118 and 121* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response, Amendment and Applicant's Arguments/Remarks, all filed 09/15/08 is acknowledged.

Claims 73, 75, 80, 81, 90, 93-96, 99, 101, 105-109 and 117-121 are pending in this action. Claims 73, 75, 80, 81, 90, 101 and 105 have been amended. Claims 1-72, 74, 76-79, 82-89, 91, 92, 97, 98, 100, 102-104 and 110-116 have previously been cancelled. Claims 73, 75, 80, 81, 90, 99, 101, 105, 117, 118 and 121 remain rejected. Claims 93-96, 106-109, 119 and 120 are allowed.

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 73, 75, 80, 81, 90, 99, 101, 105, 117, 118 and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aberg *et al.* (hereafter "Aberg") (U.S. Pat. No. 5,731,319) in view of Hellberg *et al.* (hereafter "Hellberg") (U.S. Pat. No. 6,372,802).

Aberg *et al.* ('319) teach methods and compositions for the treatment of allergic rhinitis comprising descarboethoxyloratadine – "DCL" (desloratadine) that avoids adverse side effects associated with other non-sedating antihistamines (see Abstract); (col. 3, line 21 – col. 4, line 21). The descarboethoxyloratadine daily dose range is from about 0.1 mg to less than about 10 mg, administered orally in single or divided doses (col. 8, lines 30-41). (This range encompasses

and meets Applicant's range of "about 2.5 mg" and "about 5 mg" desloratadine of instant claims 90 & 105). Suitable antioxidants (*i.e.*, organic acids) are disclosed at column 9, lines 12-30. The compositions can also include starches, sugars, microcrystalline cellulose, diluents, granulating agents, lubricants, binders, disintegrating agents and the like (col. 9, lines 31-39). Solid oral dosage forms such as tablets are preferred (col. 9, line 40 – col. 10, line 13).

With regards to the claim limitation of the "total amount of desloratadine degradation products being less than or equal to 2% by weight", it is the position of the Examiner that Aberg recognizes and teaches the use of the same acids as claimed by Applicant, which would also be fully effective in protecting desloratadine from the formation of degradation products; thus the total amount of degradation products of the prior art formulation would be minimal. Moreover, Applicant has not established criticality of the claimed amounts of degradation products, nor have any unexpected results been observed through the claimed amounts.

With respect to the claimed amounts of antioxidants, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding Applicant's limitation of desloratadine in a "free base form", it is the position of the Examiner that Applicant has not demonstrated any unusual results that would accrue as a result of the active ingredient (desloratadine) being provided in its free base form. The prior art

explicitly teaches use of the same drug in combination with the same additional components (i.e., citric acid) to treat the same problems as sought by Applicant.

With regards to the claimed dissolution of desloratadine, being "at least 80% desloratadine dissolved in a 0.1N HCL solution at 37°C in about 45 minutes", this dissolution rate limitation is not explicitly disclosed by Aberg. However, the determination of a suitable or effective rate of dissolution is within the level of one of ordinary skill in the art, obtained through routine or manipulative experimentation to obtain optimal results. Absent a showing of evidence to the contrary, the claimed dissolution rate, would be obvious to one of ordinary skill in the art given the explicit teachings of Aberg. Furthermore, no unexpected or superior results have been demonstrated through Applicant's claimed desloratadine dissolution rate.

Aberg do not teach edetate disodium.

Hellberg *et al.* ('802) teach methods and compositions for treating allergic diseases such as allergic rhinitis or sinusitis comprising disulfide derivatives (Abstract); (col. 3, lines 40-54). Conventional excipients that are added to the composition are chelating agents or stabilizers. Edetate disodium is disclosed as the suitable chelating agent or stabilizer (col. 3, lines 1-23). Active ingredients disclosed include antihistamines, such as desloratadine (col. 3, lines 24-39). Administration forms comprise oral dosage forms such as tablets (col. 2, lines 43-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate conventional chelating agents or stabilizing agents, such as edetate disodium as taught by Hellberg *et al.* within the formulations of Aberg *et al.* One of ordinary skill in the art would do so because Hellberg *et al.* explicitly teach the use of conventional

excipients such as chelating or stabilizing agent and particularly teach edetate disodium as an effective and suitable chelating/stabilizing agent, useful for protecting against any degradation products. The expected result would be an enhanced dosage form and composition for combating allergic disorders and diseases.

Thus, given the teachings of Aberg and Hellberg, the instant invention, when taken as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 09/15/08 have been fully considered but they are not persuasive.

- **Rejection under 35 U.S.C. §103(a) over Aberg ('319) in view of Hellberg ('802):**

Applicant argued, "The term antioxidant is not mentioned in this passage. Rather, organic acids are mentioned in the context of preparing a pharmaceutical salt for DCL."

This argument has been considered but was not found persuasive. It is of no moment that the prior art does not explicitly recite or teach that the organic acids are "antioxidants" since the component is the same and thus, it would be expected that the component (i.e., citric acid) would impart the same beneficial properties and results as that desired by Applicant. The fact that the prior art does not teach the organic acid as "antioxidants" does not in any way deter one of ordinary skill in the art from using that ingredient in their formulation. The prior art clearly teaches the use of citric acid, which is also employed by Applicant and is shown to be a suitable

ingredient. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Furthermore, Applicant's argument that "Applicant's claimed invention contemplates a composition in which the desloratadine remains in a free base form and does not create a pharmaceutically acceptable salt" was not persuasive since the instant claims do not preclude use of the organic acids for use in the preparation of a pharmaceutical salt. Applicant has not demonstrated any unusual results that would accrue as a result of the active ingredient (desloratadine) being provided in its free base form. The prior art explicitly teaches use of the same drug in combination with the same additional components (i.e., citric acid). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Applicant argued, "Aberg teaches away from what would be considered a pharmaceutically acceptable antioxidant; organic acids such as stearic acid, hydroxycarboxylic acid and ascorbic acid cause discoloration and instability of desloratadine…".

This argument was not persuasive. The instant "comprising" claim language permits additional components asides from those instantly recited, including use of various organic acids, such as the stearic acid, hydroxycarboxylic acid and ascorbic acid disclosed by Aberg, which Applicant argues as being unsuitable based on discoloration and instability. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.

See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended.").

Applicant argued, "Hellberg does not rectify the deficiencies in the teachings of the Aberg patent."

This argument was not deemed convincing, as Hellberg was relied upon for the teaching that it is well known in the art to employ the excipient (edetate disodium) in combination with desloratadine and thus is ample for all that it teaches. Moreover, as delineated above, Applicant has not sufficiently established that the free base form would yield any unexpected or surprising results over the teachings of the combined art of record.

The rejections of record have been maintained.

* * * * *

Allowable Subject Matter

Claims 93-96, 106-109, 119 and 120 are allowed.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

January 05, 2009